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PATENT AND  
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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY  
AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PO BOX 1450, ALEXANDRIA, VA 22313-1450  
WWW.USPTO.GOV

CSABA HENTER  
MILLEN, WHITE, ZELANO & BRANIGAN  
ARLINGTON COURTHOUSE PLAZA I  
2200 CLARENDON BOULEVARD, SUITE 1400  
ARLINGTON, VA 22201

#19

In re Application of :  
Peter Holscher et al :  
Serial No.: 09/787,396 : PETITION DECISION  
Filed: March 19, 2001 :  
Attorney Docket No.: SCH-1706 :

This is a decision on the petition under 37 CFR 1.181, filed April 15, 2003, to withdraw an election/restriction (sic - Lack of Unity) requirement as improper.

#### BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 371 as the National Phase of PCT/EP99/07089 with claims 1-15. A preliminary amendment filed with the application was never entered. In a first Office action mailed to applicants on November 30, 2001, the examiner held Lack of Unity between Group I, oxazines, Group II, thiazines, and Group III, selinazines for claims 1-10, holding claims 11-13 as non-statutory, claim 14 as directed to multiple uses and claim 15 to an apparent starting material.

Applicants replied on December 20, 2001, electing Group I to oxazines, offering a perfunctory traverse that the examiner had not sustained a serious burden for examining all claims.

On February 19, 2002, the examiner mailed a new Office action maintaining the Lack of Unity for reasons of record and holding claims 11-15 as non-elected. Claims 1-10 were rejected under 35 U.S.C. 112, first and second paragraphs as indefinite and lacking description in the specification. Claims 1-10 were also rejected under 35 U.S.C. 103 as unpatentable over WO/98/50372. Claim 10 was also indicated as not complying with 37 CFR 1.141.

Applicants replied on February 19, 2002, amending claims 1 and 6-15, canceling claims 2-5 and adding claims 16-18. Applicants addressed by amendment many of the rejections under 35 U.S.C. 112, first and second paragraph by limiting the claims to oxazines. The objection to claim 10 under 37 CFR 1.141 as also addressed. A certified translation was supplied to overcome the rejection under 35 U.S.C. 103.

The examiner mailed a new Office action to applicants on July 17, 2002, examining claims 1, 6-10 and 16-18. Claims 11-15 were maintained as non-elected. Claims 1, 6-10 and 16-18 were again rejected under 35 U.S.C. 112, first and second paragraph. No mention of the Lack of Unity requirement was made.

Applicants replied on October 17, 2002, by further amending claims 1, 6 and 18, canceling claim 16 and adding claims 19-22. The rejections under 35 U.S.C. 112, first and second paragraphs were addressed. No mention of the restriction requirement was made.

The examiner mailed a new Office action to applicants on November 5, 2002, rejecting claim 1 under 35 U.S.C. 103 over the compounds excepted by provisos based on similarity thereto.

Applicants replied on March 5, 2003, by further amending claim 1 without further argument.

The examiner mailed a new Office action to applicants on March 18, 2003, setting a one month shortened statutory period for reply indicating claims 1, 6-10 and 17-22 allowable and requiring cancellation of non-elected claims 11-15.

#### DISCUSSION

Applicants request that the examiner be directed to examine claims 11-15. It is noted that applicants made only a perfunctory traverse of the Lack of Unity requirement in replying thereto and the traverse appears to be related to the reasons for restriction under 35 U.S.C. 121 and 37 CFR 1.141. An issue was raised by the examiner under 37 CFR 1.141 in the next Office action and addressed by applicants. No other reply continues the traversal of the requirement.

Applicants argue that examination of all claims would not constitute an undue burden on the Office or examiner. However this standard is not applicable in cases filed under 35 U.S.C. 371. In this instance Lack of Unity is the applicable standard and PCT Rule 13 sets forth general guidelines for making a Lack of Unity holding. Therein it is noted that a compound and/or its composition initially should be found to have unity with an especial process for making the compound or composition and an especial process for using the compound or composition.

In the first Office action claims 11-15 were held to be non-statutory (11-13), directed to multiple processes of making (14) and a starting material (15). Following election of the oxazine compounds examination commenced on the elected compounds, claims 11-15 being held as non-elected (or improper). Following a first action on the merits, extensive amendments were made to the claims, including claims 11-15. Claim 11 was placed in proper format as a pharmaceutical composition based on the compound. Claims 12-13 were amended to claim an especial use of the composition. Claim 14 was drafted to an especial process for making the compound and claim 15 was drafted to claim a starting material or intermediate for preparing the compounds. However, the examiner continued to hold these claims as non-elected.

It is well established that a composition claim cannot be separated from the compound on which it is based, especially where the additional components of the composition lend no patentable weight to the determination of patentability, as here. Only commonly accepted adjuvants, etc., are set forth as components of the composition based on the compound. Thus claim 11 is properly

examined with the compound. Claims 12-13 are directed to the use of the composition for a specific treatment and should also be examined with the compound/composition claims in accordance with the guidelines of PCT Rule 13.

Claim 14 is directed to an especial method of making the final compound and thus qualifies under the guidelines of PCT Rule 13 to be examined with the compound of claim 1.

Claim 15, however, is shown as a starting material (or intermediate) in the preparation of the compounds of claim 1 and, as argued by applicants, should also be included with examination of the compounds of claim 1. However, a review of claim 15 shows that it is directed to both oxazine and thiazine precursor compounds. As such it is not directed solely to the compounds of claim 1 and may therefor be excluded from examination. If amended to be limited to precursors of claim 1 only it would be examinable with the compounds of claim 1.

Applicants' petition under 37 CFR 1.181 is **GRANTED-IN-PART**.

**The last Office action is withdrawn and the application will be returned to the examiner for examination of claims 11-14 in addition to claims 1, 6-10 and 17-22, already examined. If properly amended, claim 15 would also be subject to examination.**

Should there be any questions with respect to this decision, please contact William R. Dixon, Jr., by mail addressed to: Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (703)308-3824 or by facsimile transmission at (703) 305-7230.



Bruce M. Kisliuk  
Director, Technology Center 1600